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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,023	07/18/2006	Esa Suokas	12808/29	9012

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EXAMINER	
HORNBERGER, JENNIFER LEA	
ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,023	SUOKAS ET AL.	
	Examiner	Art Unit	
	JENNIFER L. HORNBERGER	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) *28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: The device as claimed can be used in a materially different method such as sewing two pieces of fabric together. The device as claimed can be used in a materially different process such as inducing cavities through hydrophilic polymer dissolving in an aqueous environment.

2. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 28-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al (EP 1157708) in view of Vogt et al. (US 2008/005878733). Regarding claim 1, Fischer et al. disclose a multifunctional synthetic bioabsorbable device comprising: a synthetic bioabsorbable polymeric matrix, particles of a pharmacological

agent (paragraph 7). Fischer et al. fail to disclose cavities induced around the particles of the pharmacological agent dispersed in said synthetic bioabsorbable polymeric matrix, said cavities existing in said matrix as a result of mechanical processing of a mixture of the matrix and said particles. However, Vogt et al. disclose cavities encapsulating a solid pharmacological agent (paragraphs 9 and 10). Therefore, it would have been obvious to one of ordinary skill in the art induce cavities around the pharmacological agent of the device of Fischer et al. to provide for more reliable and consistent drug delivery in view of Vogt et al. (paragraphs 9 and 10). The claimed phrase "as a result of orientation and mechanical solid-state processing of a mixture of the matrix and said particles, wherein the pharmacological agent retains its solid particulate form in the melt-processing temperature of the matrix" is being treated as a product by process limitation; that is the cavities existing in the matrix are formed by orientation and mechanical solid state processing of a mixture of the matrix and said particles, wherein the pharmacological agent retains its solid particulate form in the melt-processing temperature of the matrix. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

Regarding claim 2, Fischer et al. in view of Vogt et al. disclose the claimed invention except for the shape of the cavities. It would have been an obvious matter of design choice to determine the shape of the cavities, since applicant has not disclosed that the shape solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with circular cavities. Further, since said cavities cause reduced Young's modulus and increased elasticity, it would be reasonable to expect that the device of Fisher et al. in view of Vogt et al. also having cavities would have the same properties.

Regarding claim 3, Fischer et al. disclose the device is a suture, fiber, thread, cord, or wire (paragraph 7).

Regarding claims 4 and 5, Fischer et al. disclose the device is a mesh (paragraph 18) comprising fibers of differing bioabsorbable properties (paragraph 10).

Regarding claim 6, Fischer et al. disclose the mesh comprises bioabsorbable fibers and non-bioabsorbable fibers, or fibers of differing bioabsorption rates (paragraph 10).

Regarding claims 7-9, Fischer et al. disclose the pharmacological agent is an antibiotic in that it inhibits bacterial growth (paragraph 7).

Regarding claims 10-12, Fischer et al. disclose the pharmacological agent comprises 0.01 to 50 wt-% of the weight of the said multifunctional device (paragraph 16).

Regarding claims 13-15, Fischer et al. discloses the claimed invention except for said pharmacological agent comprises 1-10 wt-% of the weight of the said

multifunctional device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to ascertain the effective minimum and maximum amounts of the pharmacological agent, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 16-18, Fischer et al. discloses the said multifunctional device is monofilamentous in its structure (paragraph 7, ln 41).

Regarding claims 19-21, Fischer et al. discloses the said multifunctional device is multifilamentous in its structure (paragraph 10).

Regarding claims 22-24, Fischer et al. disclose the said multifunctional device has a drug releasing function effective to inhibit bacterial attachment and biofilm formation (paragraph 7, line 43).

Regarding claim 25, Fischer et al. discloses it is made by melt or solution processing technique and subsequent processing method (paragraph 15).

Regarding claim 26, Fischer et al. discloses the subsequent processing method is fiber spinning (paragraph 15).

Response to Arguments

5. Applicant's arguments filed 08/20/2008 have been fully considered but they are not persuasive. With respect to applicant's arguments that Vogt et al. fail to disclose cavities as a result of mechanical processing, the claimed phrase "result of orientation and mechanical solid-state processing of a mixture of the matrix and said particles, wherein the pharmacological agent retains its solid particulate form in the melt-

processing temperature of the matrix" is being treated as a product by process limitation as stated above.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
10/16/08

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731